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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,026	02/25/2002	David James Hallett	T1502	5905

7590 05/19/2003

Merck & Company Inc
126 East Lincoln Avenue
Rahway, NJ 07065

EXAMINER
SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/19/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,026	HALLETT ET AL.	
	Examiner	Art Unit	
	Robert Shiao	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *application received on 02/25, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,9 and 10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This application claims benefit of the foreign application:

United Kingdom 9921150.0 with a filing date 09/07/1999.

2. Claims 1-7, and 9-10 are pending in the application.

Election/Restrictions

3. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g., Y, R^3, and Z in claim 1, and their widely divergent meanings, a precise listing of inventive groups cannot be made. The following groups are exemplary:

I Claims 1-7, and 9-10, drawn to products of the formula I, wherein Y is defined as in claim 1, Z is morpholine, morpholine (C_{1-6}) alkyl, or NR^1R^2, and R^1 and R^2 are independently morpholine or piperazine, R^3 is phenyl or furan, their processes for making, and their methods for use. If this group is elected, an election of single disclosed species also is required.

II Claims 1-7, and 9-10, drawn to products of the formula I, wherein Y is defined as in claim 1, Z is pyridine, pyridine (C_{1-6}) alkyl, pyrrolidine, pyrrolidine(C_{1-6}) alkyl, or NR^1R^2, and R^1 and R^2 are independently pyridine or pyrrolidine , R^3 is phenyl or furan, their processes for making, and their

methods for use. If this group is elected, an election of single disclosed species also is required.

III Claims 1-7, and 9-10, drawn to products of the formula I, wherein Y is defined as in claim 1, Z is pyridine, pyridine (C_{1-6}) alkyl, or NR^1R^2, and R^1 and R^2 are independently pyridine or pyridine, R^3 is morpholine or piperazine, their processes for making, and their methods for use. If this group is elected, an election of single disclosed species also is required.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The claimed compound contains a 3H-imidazo[4,5-b] pyridine moiety, which does not define a contribution over the prior art (as can be seen by the compound of CAS:115:135998).

The substituents on the imidazole vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unit of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter impose a burden on any examination of the claimed subject matter.

Applicants are required to elect a single disclosed species of compound from whichever group is ultimately elected. Upon election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the examiner for examination along with the elected species.

4. Applicants are advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (703) 308-4002. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

R.S.

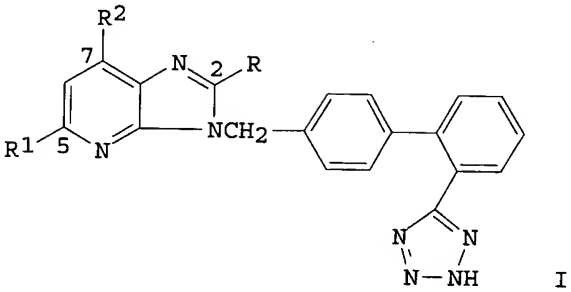
Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

May 12, 2003

US6114358

L4 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2003 ACS
ACCESSION NUMBER: 1991:535998 CAPLUS
DOCUMENT NUMBER: 115:135998
TITLE: Potent, orally active imidazo[4,5-b]pyridine-based angiotensin II receptor antagonists
AUTHOR(S): Mantlo, Nathan B.; Chakravarty, Prasun K.; Ondeyka, Debra L.; Siegl, Peter K. S.; Chang, Raymond S.; Lotti, Victor J.; Faust, Kristie A.; Schorn, Terry W.; Chen, Tsing Bau; et al.
CORPORATE SOURCE: Explor. Chem., Merck Sharp and Dohme Res. Lab., Rahway, NJ, 07065, USA
SOURCE: Journal of Medicinal Chemistry (1991), 34(9), 2919-22
CODEN: JMCMAR; ISSN: 0022-2623
DOCUMENT TYPE: Journal
LANGUAGE: English
GI



I

AB Several title Angiotensin II (AII) antagonists I (R = Et, Pr, Bu, R1 = R2 = H, Me; R1 = Me, R2 = H; R1 = H, R2 = Me) were prepd. Substituents at the 2, 5, and 7-positions of the imidazopyridine have a profound effect on the in vitro binding affinity to AII receptors (rabbit aorta membrane prepn.) and on the inhibition of the AII-induced pressor responses in conscious rats. The most active compd., I (R = Et, R1 = R2 = Me) is extremely potent in vitro (IC50 = 0.3 nM, rabbit aorta), and in vivo (ED50 = 0.048 mg/Kg i.v. and 0.026 mg/Kg p.o., conscious rat). This compd. is a specific AT1 antagonist, and substantially lowers the blood pressure of high renin hypertensive rats upon oral dosing (0.1 and 0.3 mg/Kg) with a duration of action exceeding 24 h.

IT **135145-94-7P**
RL: SPN (Synthetic preparation); PREP (Preparation)
(prepn. and Angiotensin II antagonist activity of)

RN 135145-94-7 CAPLUS

CN 3H-Imidazo[4,5-b]pyridine, 2-butyl-5,7-dimethyl-3-[2'-(1H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]- (9CI) (CA INDEX NAME)